REMARKS:

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Claim Rejections – 35 U.S.C. § 112

Applicant acknowledges the quotation of 35 U.S.C § 112, first paragraph.

Claims 1, 2 and 6-11 stand rejected under 35 U.S.C § 112, first paragraph. The Office states that, the specification, while being enabling for a method of treating a tumor in vivo comprising identifying an individual with a tumor, intratumorally introducing at least one non-coding nucleic acid sequence to at least one tumor of the individual and applying an energy source to the at least one tumor transfected with the non-coding nucleic acid sequence, does not reasonably provide enablement for a method of treating a tumor in vivo comprising introducing at least one non-coding nucleic acid to at least one tumor using a genus of administration routes and applying an energy source to the at least one tumor. The Office concludes that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Office has concluded that the claimed invention lies in the field of cancer gene therapy. The Office provides a discussion of the state of the art of cancer gene therapy, citing several references. The Office has determined that at the time the application was filed, the state of the art for gene therapy was considered highly unpredictable. As such, the Office concludes that given the lack of sufficient guidance as to a gene therapy effect produced by any nucleic acid cited in the claims, one skilled in the art would have to engage in a large quantity of

experimentation in order to practice the claimed invention based on the applicants' disclosure and the unpredictability of gene therapy.

In view of the amendment to the claims, Applicant respectfully traverses the finding of the Office regarding the rejection of claims 1, 2 and 6-11 under U.S.C. 112, first paragraph.

The present invention does not lie in the field of cancer gene therapy. In general, gene therapy is the transfer of genetic information into cells and tissues to achieve some desired effect. In humans, gene therapy is typically used to treat or compensate for a genetic mutation in the cellular genetic machinery or to enhance the production of a certain protein. The steps in gene therapy include, isolating the gene coding for the desired protein, delivering the gene to a target cell by means of a vector, integrating the gene into the cell such that the cell begin to produce DNA and RNA coding for the protein, the protein produced by the cell then acts inside the cell or is released into the environment and then stimulates the desired action.

The present invention does not describe a method of treating cancer through gene therapy. As previously described, gene therapy requires that the gene that is introduced to a target cell be a gene that codes for a desired protein, such that the protein is produced by the cell upon an effective treatment procedure. By contrast, the gene that is delivered to a tumor cell in accordance with the present invention is a non-native gene. As described at paragraph [0030] of the specification, a non-native gene is a gene that does not code for a known transcription or translation product for the subject receiving treatment. As such, a non-native gene in accordance with the present invention may be defined as a non-coding nucleic acid sequence that does not code for a therapeutic protein of the treatment subject.

Claim 1 has been amended to more clearly describe that which the applicant regards as the invention. Amended claim 1 describes a method of eliciting an antitumor effect in vivo comprising the steps of, identifying a treatment subject, identifying at least one non-coding nucleic acid sequence, wherein the non-coding nucleic acid sequence is not associated with the expression of a gene of the treatment subject, intratumorally introducing the at least one non-coding nucleic acid sequence to at least one tumor cell in the treatment subject, applying energy from an energy source to the at least one tumor cell, the application of the energy effective in eliciting an antitumor effect.

Applicant believes that the specification does enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the amended claims, and as such, the specification is enabling for claims 1, 2, and 6-11 as presented.

Claim Rejections – 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C § 102(b), 35 U.S.C § 102(e), and 35 U.S.C § 102(f).

Claims 1, 2 and 6-11 stand rejected under 35 U.S.C § 102(b) as being anticipated by Dev et al. (U.S. 5,993,434). The Office states that Dev et al. teaches delivering nucleic acids to tumor cells and using electrical pulses on the tumor cells and that Dev teaches using antisense nucleic acids or triplex agents that are associated with the expression of a gene, nucleic acid sequences that interfere with the gene's expression at the translational level for treating a cell proliferative disorder. The Office has concluded that antisense molecules are equivalent to non-coding nucleic acid sequences that do not encode a therapeutic protein.

In view of the amendment to the claims, Applicant respectfully traverses the finding of the Office.

With reference to paragraphs [0030] and [0031] of the patent application as originally filed, the non-coding nucleic acid sequences described and claimed in accordance with the present invention do not code for a transcription or translation product of a therapeutic protein of the host organism and, as such, the non-coding nucleic acid sequence in accordance with the present invention is not associated with the expression of a gene of the treatment subject. Claim 1 has been amended to better define that which the applicant regards as the invention. Accordingly, the non-coding nucleic acid in accordance with the present invention is a nucleic acid that is not associated with the expression of a gene of the treatment subject.

As indicated by Dev et al. at col. 9, it is sometimes desirable to modulate the expression of a gene in a cell by the introduction of a molecule, wherein the term "modulate" envisions the

suppression of expression of a gene when it is over-expressed, or augmentation of a gene when it is under-expressed. Where a cell proliferate disorder is associated with the expression of a gene, nucleic acid sequences that interfere with the gene's expression at the translational level can be used. In an exemplary embodiment, Dev suggests the use of molecules, such as antisense nucleic acids, to block translation of a specific mRNA. Clearly, the antisense molecule, as described by Dev et al. is associated with the expression of a gene of the species when the antisense molecule is used to modulate the expression of a gene in a cell.

Amended claim 1, recites the limitation that the non-coding nucleic acid in accordance with the present invention is not associated with the expression of a gene of the treatment subject. Accordingly, the non-coding nucleic acid as defined by the present invention is not used to modulate the expression of a gene by suppressing the expression of a gene when it is over-expressed, or augmenting the gene when it is under-expressed.

As such, Applicant believes that the amendment to Claim 1 is effective in overcoming the rejection by the Office. More specifically, the non-coding nucleic acid of the present invention is defined and claimed to be a nucleic acid that is not associated with the expression of a gene, which is not equivalent to the antisense molecules as described by Dev et al.

Claims 2 and 6-8 are dependent upon Claim 1 and are therefore allowable as a matter of law.

Claims 1, 2 and 6-8 stand rejected under 35 U.S.C. 102(e) as being anticipated by Dev et al., (U.S. 6,569,149). Claims 1, 2 and 6-8 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter in view of Dev et al., (U.S. 6,569,149), Dev et al. (U.S. 5,993,434) and Dev et al. (U.S. 6,451,002).

The Office states Dev et al. teaches using antisense molecules in the method and that antisense molecules are non-coding nucleic acid sequences that do not encode a therapeutic protein.

Applicant has amended Claim 1 to more clearly define that which the applicant regards as the invention. Specifically, Claim 1 includes the limitation that a non-coding nucleic acid for use in the present invention is a nucleic acid that is not associated with the expression of a gene of

the treatment subject. As described by the Office, an antisense molecule is a non-coding nucleic acid sequence that does not encode a therapeutic protein. However, as previously described, an antisense molecule is defined as being effective in modulating the expression of a gene by suppressing the expression of a gene, and as such, the antisense molecule as described by Dev et al. is associated with the expression of a gene of the treatment subject. Additionally, the Office states on pg. 14 of the Final Office Action that the Dev '434 reference teaches, "using antisense nucleic acid or triplex agents that are associated with the expression of a gene, nucleic acid sequences that interfere with the gene's expression at the translational level for treating a cell proliferative disorder". In view of the amendment to independent Claim 1 and the arguments presented, Applicant believes that the rejections under 35 U.S.C. 102(e) and under 35 U.S.C. 102(f) have been overcome and that Claim 1 is now believed to be in condition for allowance.

Claims 2 and 6-8 are dependent upon Claim 1 and are therefore allowable as a matter of law.

Claim Rejections – 35 U.S.C. § 103

Applicant acknowledges the quotation of 35 U.S.C § 103(a).

Claims 1, 9 and 10 stand rejected under 35 U.S.C § 103(a) as being unpatentable over Dev et al., (U.S. 5,993,434) taken with Heller et al. (6,714,816).

For the reasons cited above with regard to the 35 U.S.C § 102 rejections under Dev et al, (U.S. 5,993,434), Applicant believes that the amendment present to Claim 1 is effective in overcoming this rejection and that Claim 1 is patentable over Dev et al., (U.S. 5,993,434) in view of Heller et al. (6,714,816).

Claims 9 and 10 are dependent upon Claim 1, which has been shown to be allowable, and are therefore allowable as a matter of law.

Claims 1, and 11 stand rejected under 35 U.S.C § 103(a) as being unpatentable over Dev et al., (U.S. 5,993,434) taken with Chiocca et al. (U.S. 5,688,773).

For the reasons cited above with regard to the 35 U.S.C § 102 rejections under Dev et al, (U.S. 5,993,434), Applicant believes that the amendment present to Claim 1 is effective in overcoming this rejection and that Claim 1 is patentable over Dev et al., (U.S. 5,993,434) in view of with Chiocca et al. (U.S. 5,688,773).

Claim 11 is dependent upon Claim 1, which has been shown to be allowable, and is therefore allowable as a matter of law.

Claim Rejections – Double Patenting

Claims 1, 2 and 11 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 3 of U.S. Patent No. 6,569,149. Claims 1, 2 and 6-8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,451,002. Claims 1, 2 and 6-8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,993,434. Claims 1, 2, 9 and 10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 3 of U.S. Patent No. 6,569,149 in view of Heller et al. (U.S. 6,714,816). As such, the Office has concluded that the cited claims of the present invention are not patentably distinct from the conflicting claims cited in the references.

In view of the amendment presented to Claim 1, and for the argument previously presented, Applicant believes that amended independent Claim 1 is patentably distinct from the conflicting claims presented in the cited references and is therefore believed to be in condition for allowance. More specifically, the cited references do not claim the introduction of a non-coding nucleic acid sequence that does is not associated with the expression of a gene of the treatment subject as claimed by the present invention.

Claims 2 and 6-11 are dependent upon Claim 1, and are therefore allowable as a matter of law.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

Molly Sauter

By:_____

Dated: July 8, 2005

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CERTIFICATE OF FACSIMILE TRANSMISSION
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment AF is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 1635, Attn.: Brian A. Whiteman, (703) 872-9306 on July 8, 2005.

Dated: July 8, 2005

Shelley Butz

Shelley Butz